

A Study of Dengue Tetravalent Vaccine (TDV) in Adults (Age 45 to 60 and >60 to 79 Years)

NCT06579755

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	800 participants

Key Eligibility Criteria

Inclusion (5)

- Participant is aged 45 to 79 years at the time of entry into the trial.
- Participant is male or female.
- Participant is in good health or has a medical diagnosis of one or more of diabetes mellitus, hypertension, or chronic kidney disease (that is, comorbidities) and are medically stable in the opinion of the investigator at the time of entry into the trial, as determined by medical history and targeted physical examination. Medically stable is defined as no change in diagnoses or chronic medications (dose or class) for medical reasons in the 3 months prior to participating in the trial.
- Participant has signed and dated a written informed consent form and any required privacy authorization prior to the initiation of any trial procedure, and after the nature of the trial has been explained according to local regulatory requirements.
- Participant can comply with trial procedures and is available for the duration of follow-up.

Exclusion (34)

- Participant has contraindication(s), warning(s), and/or precaution(s) applicable to vaccination with TDV as specified in the Investigator's Brochure and/or approved product label (as applicable) in the participating country.
- Participant has a known hypersensitivity or allergy to any of the TDV or placebo components (including excipients).
- Participant has behavioral or cognitive impairment or psychiatric disease that, in the opinion of the investigator, could interfere with the participant's ability to take part in the trial.
- Participant has a history of progressive or severe neurologic disorder, seizure disorder or neuro-inflammatory disease (example, Guillain-Barré syndrome).
- Participant has an illness, or history of any illness that, in the opinion of the investigator, might interfere with the results of the trial or pose additional risk to the participant due to involvement in this trial.

... and 29 more (see full listing online)

Locations (7 total)

Fundacion Huesped - PPDS, Buenos Aires, Argentina

Associacao Obras Sociais Irma Dulce Hospital Santo Antonio, Salvador, Estado de Bahia, Brazil

Fundacao Faculdade Regional de Medicina de Sao Jose Do Rio Preto Hospital de Base - PPDS, São José do Rio Preto, São Paulo, Brazil

... and 4 more locations

<https://clinicaltrials.gov/study/NCT06579755>

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